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Ecuador

Biotechnology

Ecuador Standing Biotechnology Report 2005

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Report Highlights:

Ecuador does not have a specific national law on Biotechnology and Biosafety. However, the country signed and ratified the Cartagena Protocol on Biosafety, and is currently in the process of issuing General Rules on Biosafety that will ease application of the protocol, which is considered as national law in Ecuador.

Includes PSD Changes: No
Includes Trade Matrix: No
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SECTION I. EXECUTIVE SUMMARY

Ecuador does not have a specific law that regulates biotechnology and its application. However, a proposed General Rule that invokes the precautionary principle and calls for labeling is currently out for public comment. Ecuador imports –mainly from the United States and Argentina- almost 60 percent of its corn demand, 99 percent of cotton, 98 percent of wheat, and 90 percent of soybean meal, which enter without any specific requirements related to biotechnology. The animal feed as well as the poultry, pork and snacks industries currently use these products in their formulations, and it is unlikely that Ecuador would have the capacity to supply their growing demand in the near future. Therefore, the possible issuance of restrictive rules not only would hurt U.S. export interests, but would also complicate the survival of these local industries.

Ecuador ratified the Cartagena Protocol on Biosafety in November 2002. Ecuador's general policies on Biosafety are expressed in several existing laws, and the Constitution of Ecuador amended in 1998, includes general provisions related to biosafety and environmental protection. Article 89 of Ecuador's Constitution mandates that the Government will take all measures to "regulate, under strict biosafety standards, the propagation, research, use, trade, and importation of genetically modified organisms".

SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION

According to the Ecuadorian Institute for Agricultural Research (INIAP), given the incipient technology and infrastructure available, Ecuador does not have the capacity to conduct any GMO-related research; therefore it does not commercially produce any biotechnology crops. However, INIAP conducts genetic research to improve the quality of seeds through hybrids for cocoa, potatoes, tomato, corn, rice and soybeans.

Furthermore, given the inexistence of biotechnology legislation, Ecuador does not allow importation of seeds containing GMOs. According to the Ministry of Agriculture, all seeds used for rice, corn, soybean and other plantations are either hybrids developed by the INIAP or other certified imported seeds that do not contain GMOs, and which have passed through a rigorous in-country certification process.

On the other hand, a growing proportion of the supply of corn, cotton, soybean meal and wheat for industrial use is of foreign origin. A brief description of the commercial situation of these products follows:

- Presently, Ecuador imports 57 percent of its corn demand. Imports reached 384,000 MT in 2004, 91 percent of which originated in the United States and 9 percent in Argentina.
- Ecuador purchases 99 percent of its cotton needs from the United States, reaching 17,000 MT in 2004.
- Soybean meal imports are also rising with Argentina and Uruguay as main suppliers. However, depending on prices, in some years, Ecuador purchases important volumes of soybean meal from the United States. Overall imports in 2004 reached 312,000 MT.
- Wheat also represents an important commodity for U.S. agricultural interests in Ecuador. In the past five years Ecuador has imported an average of 400,000 MT of wheat (98 percent of its needs) from Canada and the United States.

Finally, Ecuador receives food aid from the United States since 1985, and in the past five years it has received 164,000 MT of wheat, 60,000 MT of soybean meal, and 5,000 MT of soybean oil.

SECTION III. BIOTECHNOLOGY POLICY

Regulatory Framework

According to the Environmental Management Law, the Ministry of Environment of Ecuador is the entity in charge of regulating the production, propagation, research, use, trade and importation of genetically modified organisms (GMOs). The same law under article 8 establishes the coordination authority of the Ministry of Environment over the decentralized Environmental Management System, and allows for other institutions, such as the Ministries of Agriculture, Health and Foreign Trade to have direct authority over their own relevant issues.

Although the institutions are in place, there is no specific law or regulation on biotechnology and biosafety. The environmental management law is very broad and does not deal with specific issues of agricultural biotechnology and biosafety. However, a broad national policy on biosafety is clearly expressed in existing laws. The Constitution, for example, promotes a series of guidelines regarding biotechnology; such as the right of Ecuador's people to "live in a safe and balanced environment" (article 23), the government's obligation to promote public

debate regarding decisions that may affect the environment (art. 88), the precautionary principle (art. 91), the strict regulation of biosafety (art. 89), and the protection of consumers rights (art. 92).

Other national laws such as the Environmental Management Law, the Health Code, the Consumer Rights Protection Law, the Agricultural Development Law, the Law of Seeds, and the Plant and Animal Health Law are of general applicability but do not give specific guidance on biosafety issues.

On the international front, as a signatory of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, Ecuador is obliged to issue policies and regulations in accordance with the precepts of these international agreements. Also, as a member of the Andean Community of Nations, Ecuador is subject to Andean Decision 523, which states an Andean Strategy on Biodiversity that must be taken into account by all members in issuing their regulations on biosafety.

There is a proposed text for a "Law of Conservation and Sustainable Management of the Biodiversity" (Biodiversity Law) that would serve as a framework for Ecuador's regulations on biosafety and biotechnology. However, the text was first submitted to Congress in April of 2002 and later debated without consensus. A second debate was scheduled for February of 2003, but it never happened. The reasons for delaying this law are basically political. Indigenous groups along with environmentalists continue to have negative positions on biotechnology and biosafety issues.

In the Ecuadorian legal system, international agreements such as the Cartagena Protocol on Biosafety are considered supreme law under the Constitution. In that case, given the absence of a national law on biosafety, the Executive (the President, a Ministry or group of Ministries) may issue general rules for application of an international agreement; in this case for the Protocol on Biosafety. This legal principle avoids for a set of rules to be debated and approved by Congress, thus speeding up the process.

Based on the commitments born in the Protocol on Biosafety, Ecuador is currently implementing a project called "National Biosafety Framework", which is managed by the National Biosafety Committee, an inter-institutional working group accountable to the Ministry of Environment. The mission of this committee is to issue proposed texts for the following:

- A National Policy on Biosafety
- General Rules on Biosafety (including agricultural biotechnology)
- Handbook of Procedures
- National and International Cooperation Mechanisms.

Currently, the working group has finalized the first two parts of its mandate, and a proposed text for the General Rules on Biosafety is open for public debate. However, there is uncertainty as to what would the next steps be on issuing the rules due to the conflicted political environment in Ecuador and the current Andean-U.S. Free Trade talks, which include Intellectual Property Rights and Environmental issues.

Specific Laws dealing with Biosafety and Biotechnology

Labeling: The Law for Protection of Consumer's Rights

This law, enacted on July 10 of 2000, regulates the supplier-consumer relations by promoting knowledge and protection of consumer's rights. It has a clause by which ambiguous dispositions should be interpreted to favor the consumer. The public entity in charge of enforcing this law is the Office of the Ombudsman. However, little or nothing has been done to exercise such enforcement.

On regards to Biotechnology, article 13 of this law states clearly that " in case that products sold for human or animal consumption had been produced using biotechnology or any type of genetic manipulation, labels must warn of this fact using highlighted characters". Despite this specific regulation, there are no products in the Ecuadorian market, whether imported or locally produced, that contain such warning. Article 14, furthers the explanation of labeling by declaring minimum labeling requirements for food, which should include the biotech process.

As to health and safety, this law has a supplemental character by leaving room for specific laws dealing with health protection matters to regulate specific issues. However, the non-existence of a law on biosafety and biotechnology provides that this law is currently the only one in place dealing specifically with biotechnology labeling.

Currently, an inter-institutional working group that includes Ecuador's Standardization Institute and the Ministry of Health are preparing a new standard for food labeling. The proposed text is ready for final approval and submission to the WTO for comment. Based on the provision of article 13 of the aforementioned consumer rights law, the new standard sets a requirement for biotech foods to be labeled as to contain GMOs, and for foods containing GMO ingredients to declare the percentage of such GMOs in their composition.

Imports of Vegetable Materials and Animals: Laws of Animal and Vegetable Health

Article 4 of the Vegetable Health law establishes that any import of vegetable materials for propagation, including those used for research must obtain a previous authorization from the Ministry of Agriculture. In the case of animals used for genetic improvement, the Animal Health law provides requirements and authorizations from the Ministry of Agriculture, and establishes the obligation to comply with Andean regulations.

Authorized Biotech Foods: Rules for Sanitary Registration and Control

This regulation deals with the sanitary registration of national and imported food and beverage products for human consumption in Ecuador. Article 50 of this regulation makes reference to fines and penalties, which will be applied according to the dispositions of the Consumers Rights Protection law.

Furthermore, article 54 mentions that biotech and/or GMO foods will only be authorized to enter Ecuador when such products comply with the requirements of the Ministry of Health, which would issue a positive list of transgenic products authorized for import. Such a list does not exist, and it is unlikely that it will be issued in the future.

Proposed General Rules on Biosafety

Since June of 2003, the Ecuadorian Biosafety Committee has been working on a proposed text for the general Rules on Biosafety. In May of 2005, the working group issued a text that is currently out for public comment, with the possibility of becoming law through an

executive decree signed by the President. Given the inexistence of a law on biotechnology and biosafety, the role of these general rules is to regulate and follow the precepts of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity. The rules must also be in accordance with the regional strategy issued by the Andean Community.

Applicability

These rules will be applicable to all activities related to development, research, entrance, management, production, distribution, transportation, import, export and use of viable and non-viable Genetically Modified Organisms (GMOs).

The proposal includes several principles of applicability, including the Principle of Precaution by which the government is obliged to exercise precaution in case of possible severe damage to the environment. This principle also provides that a lack of absolute scientific evidence shall not be used to delay measures to stop environmental degradation. A second principle provides that risk analysis for GMO-related activities will be conducted on a case by case basis. Finally, the release of GMOs should be made based on a step-by-step principle. This means that any GMOs to be released should undergo tests, risk analysis and evaluation, and pilot experimentation programs.

Prohibitions

Article 5 of this proposal prohibits imports of GMOs that have been rejected in their countries of origin. The entrance of certain GMOs and technologies that may affect the environment or human's health are also prohibited until scientific evidence proves on the contrary.

Authority

The Ministry of Environment, according to article 9 of the Environmental Management law, is the national authority for application of the proposed rules, with the support of other public institutions that play a role in the Decentralized Environmental Management System: The Ministries of Agriculture, Foreign Trade, Public Health and others.

GMO Research, Use and Release

The text proposal provides for two ways of using, releasing and experimenting with GMOs: Confined Use and Voluntary Release.

Confined use of high-risk and low-risk GMOs is authorized only for research with the previous authorization of the Ministry of Environment, which will issue the Environmental License. The Ministry will also keep strict control over the operations of these research facilities.

Voluntary release of GMOs into the environment is intended for all activities except trade and transportation. Whoever wants to release GMOs in the environment must request authorization from the Ministry of Environment, and among other requirements, submit an environmental impact study that estimates all possible risks. This shall be made on a case-by-case basis.

Trade

In order to trade with viable GMOs, the incumbent must request an authorization from the Ministry of Environment. Except for biotechnology seeds, all trade activities, including imports of viable GMOs will only require a risk analysis.

In the case of seeds containing GMOs, the environmental license will be issued only after the Ministry of Agriculture has provided authorization, which would be issued after the submission of an environmental impact study and a risk analysis.

Traders of non-viable GMOs destined for food should keep records of toxicity and allergic tests and copies of their import permits. These products must be labeled and customers should receive instructions for use. Traders of viable GMOs should maintain careful records of the documents for each GMO product. Information on the genetic modification of the product is also to be kept in order to ease traceability. All sales of these products must be made with the label indicating their transgenic origin, and must indicate that products for human or animal consumption should not be planted or propagated.

Finally, an authorization issued by any of the member countries of the Andean Community for a viable or non-viable GMO will automatically authorize its import and trade in Ecuador. This will happen only if the regulations of the authorizing country are not less restrictive than Ecuador's.

SECTION IV. MARKETING ISSUES

The use of biotechnology in food is a new and intricate topic for discussion in Ecuador. The majority of consumers are not aware of the existence of food products derived from the use of biotechnology, and in a country with great food insecurity like Ecuador, this may not be an issue of major concern to the poor and struggling majority. However, environmental and indigenous groups are fully aware of the issue, and although they lack scientific evidence of the implications of biotechnology, they continue to work towards keeping any biotech-related products from entering Ecuador as a requirement to preserve this country's mega-biodiversity.

There is no specific information related to the market acceptance of biotech foods. However, our perspective is that if biotech products are required special labels "alerting" of presumable harmful characteristics, the majority of Ecuadorian consumers will certainly reject them. On this point, the Principle of Precaution embodied in rule proposals and in the constitution may cause major issues of concern if lawmakers interpret it erroneously.

Another concern arises when Ecuador currently imports –basically from the United States and Argentina- almost 60 percent of its corn demand, 99 percent of cotton, 98 percent of wheat, and 90 percent of soybean meal without any specific restrictions related to biotechnology. The animal feed as well as the poultry, pork and snacks industries currently use these products in their formulations, and it is unlikely that Ecuador would have the capacity to supply this demand in the near future. Therefore, the possible issuance of restrictive rules not only would hurt U.S. export interests, but would also complicate the survival of these local industries.

In addition, Ecuador does not have either the resources or the scientific capacity to conduct high-level research on agricultural biotechnology, so it must rely on foreign technologies and research results. Also, Ecuador is not capable of submitting enough scientific evidence about the possible risks of the use of biotechnology as a way to justify restrictive trade measures against biotech foods. However, it is clear that Ecuadorian authorities are worried about the issue of "dependence" from foreign technologies for certain products, such as planting seeds. There is an increased fear from farmers that allowing biotech seeds will hurt their plantations, and that using these products will turn their production capacity into a dependency relationship with multinational corporations.

Even with the generalized misinformation about biotechnology among consumers and policymakers in Ecuador, few activities related to biotech capacity building and outreach have been carried out by government institutions. The largest program constitutes the National Biosafety Framework, which is a project co-financed by the United Nations Fund for the Environment and the World Environmental Fund that will end in August of 2005. By that time, a final product must be seen on Ecuador's policies and application rules for biotech. As explained above, those documents are currently out for public opinion, but very little outreach and zero capacity building have been undertaken due to limited availability of funds.

The U.S. Agricultural Affairs Office in Quito has been active in the past four years on issues related towards promoting biotechnology and agricultural research. In November of 2001, post organized an EMO-funded conference on Agricultural Biotechnology presented by U.S. scientists and experts, and which was directed towards local government officials involved in biotechnology and environmental issues on agriculture. Post has also made use of Cochran resources to have policy makers, key players and journalists participate in short training courses on biotechnology issues in Hawaii and Michigan. Further efforts are being made to continue with this type of assistance by using USDA's food aid programs to improve Ecuador's trade capacity by providing funds for international agricultural training and in-country research.